EXHIBIT 54

actavis
creating value in pharmaceuticals

December 24, 2007

Mr. Andrew Ciaccia
Compliance Officer
U.S. Food and Drug Administration
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Re: Third Party Audit of Unexpired Lots in Distribution

Dear Mr. Ciaccia,

Please find hereto the final update for the third party audit program performed on Actavis' drug products that remain within expiration as requested in the FDA Warning Letter (07-NWJ-06) dated January 9, 2007 and amended on February 1, 2007. As discussed in prior correspondences, Actavis hired Quantic Regulatory Services to conduct the requested audit. These audits included all associated laboratory data, including notebooks, electronic data, calculations and approval procedures, all raw material release documents, equipment usage logs, manufacturing batch records, in-process analysis, associated data, and yield calculations.

On December 21, 2007, Quantic provided Actavis with a statement indicating the audit was complete and the manufacturing and laboratory records have reliably confirmed the identity, strength, quality and purity of the marketed products.

[redacted]

This final update should satisfy the requirements set forth in the Warning letter and therefore no further updates will be provided. If you have any questions or additional comments please feel free to contact me directly at (973) 890-1440, ext 3059.

Sincerely,

DC Talbot FOR SCOTT TALBOT

Scott Talbot
Site Head of Quality
Actavis Totowa LLC

enc: Quantic review statements, September 21, 2007

Actavis Totowa LLC | 101 East Main Street Little Falls, NJ 07424 USA | t 973 890 1440 f 973 890 7980 | w www.actavis

DEFENDANT'S EXHIBIT 54

Deviation/OOS

[redacted]

CONFIDENTIAL

Quantic Regulatory Services, LLC

December 21, 2007

To: **Scott Talbot**
Site Head of Quality
Actavis Totowa, Little Falls Facility

Re: **Retrospective Batch Record Review**
Batches with Investigations, Deviations and Out-of-Specification Results

Under the Actavis Retrospective Batch Record Review Protocol ("Protocol"), the Quantic Regulatory Services, LLC ("QRS") audit of batch records for batches of product manufactured at the Little Falls, New Jersey facility of the Actavis Group and Actavis Totowa, LLC (individually and collectively, "Actavis") commenced with a review of all (i) deviations and investigations, including out-of-specification ("OOS") results, identified by Actavis as associated with any finished drug product batch released to the United States market, in whole or in part, on or before January 9, 2007, that remained within its expiry date as on the date on which the batch record review commenced (February 19, 2007), and was not recalled, seized or withdrawn from the market ("Market Batches") and (ii) any other deviations or investigations, including OOSs, that may not have been directly associated with any Market Batch that may have occurred between the time of the commencement of production of the earliest Market Batch and January 9, 2007. Based on a review of these deviations, investigations and OOSs as provided by Actavis, and in addition to a substantive review of the deviations, investigations and OOSs as set forth below, QRS identified those batch records that had associated deviations, investigation or OOSs ("Batches With Deviations").

For Batches With Deviations, QRS conducted both a deviation, investigation and OOS review, as appropriate, and a batch record review. The review was not an evaluation of current Good Manufacturing Compliance practices, except insofar as those practices were apparent from the records provided and were determined to impact the review standard set forth below. The review of the batch records included the bill of materials for the ingredients and components used for production of the finished batch through release (including relevant laboratory notebook and laboratory electronic data), but excluded packaging and labeling, as outlined in Sections III and IV of the Protocol. The review also included a review of stability data from any such Batches With Deviations as outlined in Sections III and IV of the Protocol.

As set forth in the Protocol, QRS reviewed the list of deviations, investigations and OOSs in reference to the corresponding potentially impacted Batch With Deviation, in each case as set forth on Attachment A, to evaluate whether the non-conformances or deficiencies observed in its review of the deviations, investigations or OOSs for that

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batch were likely, individually or collectively, to have had a material adverse impact on the identity, strength, quality or purity of the Batch With Deviation. QRS considered the following for each failure investigation as appropriate:

(a) The written record of investigation, including the thoroughness and adequacy of the documentation.
(b) Appropriateness as to scope and breadth, including, whether an analysis of other batches of the same product, other products and similar occurrences was warranted, and if so, whether such an analysis was conducted.
(c) Appropriateness as to depth, including identifying appropriate root cause, or, in the case of laboratory investigations, an assignable cause and elevation to the appropriate level of investigation.
(d) Adequacy of the support for the conclusions in the report, including any analyses of (i) the impact of issue under investigation on the batch under review and (ii) the impact of any corrective actions, if any, that were taken with respect to the batch under review.
(e) Any other information provided to QRS relevant to the evaluation set forth above.

In conducting the above review, QRS identified Batches With Deviations (Attachment A) which would be subject to the batch record review set forth below. QRS considered the following for each such Batch With Deviations as appropriate:

(a) The completed batch record for each Batch With Deviations, to determine whether there was any non-conformance or lack of adherence to the Master Batch Record, or entries or lack thereof that were not documented in accordance with the Master Batch Record, cGMP or Company procedures that were likely to have had a material adverse impact on the identity, strength, quality or purity of the Batch With Deviations.

(b) Recorded deviations and investigations identified and assigned to the Batch With Deviations, including any deviation(s) and investigation(s) regarding written procedures, OOSs and any deviations evident in the batch record that the Company may have failed to note or address during its review of the batch record, to determine whether there were any deviations that were likely to have had a material adverse impact on the identity, strength, quality or purity of the Batch With Deviations.

(c) The laboratory testing records included as part of the batch record to confirm compliance with specifications and standards for the Batch With Deviations.

(d) Stability or retention sample data for the Batch With Deviations, if any, to determine whether the stability data met acceptance criteria.

QRS reviewed the deviations, investigations and OOSs and the corresponding Batches With Deviations (Attachment A), in each case as supplied by Actavis, as stated above in accordance with the above-referenced Protocol. Based upon this review, it is QRS' opinion that, except as set forth below: (i) the batch record(s) reviewed for such Batches With Deviations, including the related deviations, investigations and OOSs, in each case as set forth on Attachment A, did not contain non-conformances or deficiencies (as set forth in Sections III.A and III.B of the Protocol) that were likely to have had a material adverse impact on the identity, strength, quality or purity of such Batches With Deviations; (ii) the laboratory testing records included as part of the such batch record(s) demonstrate satisfaction with release specifications for such Batches With Deviations; and (iii) applicable stability or retention sample results, if any, for the referenced Batches With Deviations met applicable specifications as provided by Actavis.

Notwithstanding the foregoing, the following batches (originally part of Batches With Deviations) are not included on Attachment A (Batches With Deviations), and therefore not subject to the opinion above, for the reasons stated below:

[redacted]

Quantic Regulatory Services, LLC
Senior Project Leader

12/21/07
Date

Quantic Regulatory Services, LLC
President

12/21/07
Date

Attachment A

Actavis Retrospective Batch Record Review

Batches with Investigations Deviations and Out-of-Specification Results

Item	Product Name	Batch #	Deviation, Investigation or OOS Number
1	[redacted]		
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Item	Product Name	Batch #	Deviation, Investigation or OOS Number
32	[redacted]		
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35	Digitek (digoxin tablets, USP) 0.125mg	5362A	Memo 7/20/05
36	Digitek (digoxin tablets, USP) 0.125mg	5570A	Memo 8/5/05
37	Digitek (digoxin tablets, USP) 0.125mg	5624A	Memo 8/5/05
38	Digitek (digoxin tablets, USP) 0.125mg	60992A	PD-06-013, OOSN 06-014
39	Digitek (digoxin tablets, USP) 0.25mg	60678A	LAN 06-001
40	[redacted]		
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Item	Product Name	Batch #	Deviation, Investigation or OOS Number
62	[redacted]		
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Item	Product Name	Batch #	Deviation, Investigation or OOS Number
93	[redacted]		
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Item	Product Name	Batch #	Deviation, Investigation or OOS Number
123	[redacted]		
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Item	Product Name	Batch #	Deviation, Investigation or OOS Number
156	[redacted]		
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The 322 Sample

CONFIDENTIAL

Quantic Regulatory Services, LLC

December 21, 2007

To: **Scott Talbot**
Site Head of Quality
Actavis Totowa, Little Falls Facility

Re: **Retrospective Batch Record Review**
Batches Covered in the Statistical Sampling Plan – "The 322 Sample"

Under the Actavis Retrospective Batch Record Review Protocol ("Protocol"), following the deviation, investigation and OOS review and a review of the batches containing those deviations, investigations and OOSs as set forth in the Protocol (covered by a separate letter), Quantic Regulatory Services, LLC ("QRS") completed a batch record review of batches that were part of an initial representative sampling. This sampling included each product by strength, in each case that were released to the United States market, in whole or in part, on or before January 9, 2007 and remained within their expiry date as on the date on which the batch record review commenced (May 1, 2007), and had not been recalled, seized or withdrawn from the market, as set forth in the selection plan on Attachment A ("Other Batches"). The sample consisted of 322 batches of a total of 1,469 batches meeting this criteria and distributed over this period.

For these Other Batches, QRS conducted a batch record review. The review was not an evaluation of current Good Manufacturing Compliance practices, except insofar as those practices were apparent from the records provided and were determined to impact the review standard set forth below. The review of the batch records included the bill of materials for the ingredients and components used for production of the finished batch through release (including relevant laboratory notebook and laboratory electronic data), but excluded packaging and labeling, as outlined in Sections III and IV of the Protocol. The review also included a review of stability data from any such Other Batches as outlined in Sections III and IV of the Protocol.

QRS was provided with the batch records for the Other Batches by Actavis. Those batches are identified on Attachment B. QRS considered the following for each such Other Batch as appropriate:

(a) The completed batch record for each Other Batch, to determine whether there was any non-conformance or lack of adherence to the Master Batch Record, or entries or lack thereof that were not documented in accordance with the Master Batch Record, cGMP or Company procedures that were likely to have had a material adverse impact on the identity, strength, quality or purity of the Other Batch.

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(b) Recorded deviations and investigations, if any, identified and assigned to the Other Batch, including any deviation(s) and investigation(s) regarding written procedures, OOSs and any deviations evident in the batch record that the Company may have failed to note or address during its review of the batch record, to determine whether there were any deviations that were likely to have had a material adverse impact on the identity, strength, quality or purity of the Other Batch.
(c) The laboratory testing records included as part of the batch record to confirm compliance with specifications and standards for the Other Batch.
(d) Stability or retention sample data for the Other Batch, if any, to determine whether the stability data met acceptance criteria.

QRS reviewed the Other Batches as set forth on Attachment B, in each case, as supplied by Actavis as stated above in accordance with the above-referenced Protocol. Based upon this review, it is QRS' opinion that, except as set forth below: (i) the batch record(s) reviewed for such Other Batches did not contain non-conformances or deficiencies (as set forth in Sections III.A and III.B of the Protocol) that are likely to have had a material adverse impact on the identity, strength, quality or purity of such Other Batches; (ii) the laboratory testing records included as part of the such batch record(s) demonstrate satisfaction with release specifications for such Other Batches; and (iii) applicable stability or retention sample results, if any, for the referenced Other Batches met applicable specifications as provided by Actavis.

Notwithstanding the foregoing, the following batches (originally part of Other Batches) from the sample reviewed are not included on Attachment B (Other Batches), and therefore not subject to the opinion above, for the reasons stated below:

[redacted]

Richard Cowright
Quantic Regulatory Services, LLC
Senior Project Leader

12/21/07
Date

R. S. Lukas
Quantic Regulatory Services, LLC
President

12/21/07
Date

Attachment A

CONFIDENTIAL

Proposed Statistical Sampling Plan for Actavis
Retrospective Batch Record Review

The following is the proposed sampling plan for the Actavis Retrospective Batch Record Review.

We have chosen a Limiting Quality (LQ) sample plans to evaluate the risk associated with the identity, strength, quality, and purity of the unexpired product in the market. LQ sample plans are also known as Rejectable Quality, Unacceptable Quality and Lot Tolerance Percent Defective sample plans.

The number of batch records to be reviewed will be based on the following statistically determined sample:

1. Lots with Investigations, Deviations and OOSs
   The FDA requested an audit of lots with initial OOSs, however, we have expanded this audit to include all production records that involve any deviations, investigations and OOSs within the relevant time period. This accounts for 146 of the total 1,615 records. Since this population is being reviewed in full, it will be excluded from the sample of the remaining population set forth under number 2 below.

2. Sampling Plan for all remaining 1,469 Production records
   With respect to all other batches within the relevant time period, a five percent risk sample plan (equivalent to a 95% confidence level) is proposed, with a sample size of 300 / accept on zero / 1% unaccounted for batches.

   Each SKU will be represented in the sample with no less than 10% of the total batches per SKU, or alternatively, the $\sqrt{n} + 1$, on a per SKU basis. The remaining portion of the sample batches will be selected randomly from the entire batch population.

   With respect to batch records subject to the sample plan, should a product batch record fail sample plan acceptance criteria, that is, when one sampled batch record is judged "inadequate" with a defect that prevents a determination by the review team that the deviations observed are not likely to materially adversely affect the identity, strength, quality or purity of product, the entire population should be inspected.

Attachment B

Actavis Retrospective Batch Record Review

Batches Covered in the Statistical Sampling Plan - "The 322 Sample"

Item	Product Name	Batch #
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Item	Product Name	Batch #
28	[redacted]	
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47	Digitek (digoxin tablets, USP) 0.125 mg	5367A
48	Digitek (digoxin tablets, USP) 0.125 mg	5368A
49	Digitek (digoxin tablets, USP) 0.125 mg	5568A
50	Digitek (digoxin tablets, USP) 0.125 mg	5763A
51	Digitek (digoxin tablets, USP) 0.125 mg	5768A
52	Digitek (digoxin tablets, USP) 0.125 mg	5936A
53	Digitek (digoxin tablets, USP) 0.125 mg	60038A
54	Digitek (digoxin tablets, USP) 0.125 mg	60072A
55	Digitek (digoxin tablets, USP) 0.125 mg	60221A
56	Digitek (digoxin tablets, USP) 0.125 mg	60402A

Item	Product Name	Batch #
57	Digitek (digoxin tablets, USP) 0.125 mg	60416A
58	Digitek (digoxin tablets, USP) 0.125 mg	60605A
59	Digitek (digoxin tablets, USP) 0.125 mg	60608A
60	Digitek (digoxin tablets, USP) 0.125 mg	60643A
61	Digitek (digoxin tablets, USP) 0.125 mg	60644A
62	Digitek (digoxin tablets, USP) 0.125 mg	60758A
63	Digitek (digoxin tablets, USP) 0.125 mg	60931A
64	Digitek (digoxin tablets, USP) 0.125 mg	60991A
65	Digitek (digoxin tablets, USP) 0.25 mg	51052A
66	Digitek (digoxin tablets, USP) 0.25 mg	5452A
67	Digitek (digoxin tablets, USP) 0.25 mg	5453A
68	Digitek (digoxin tablets, USP) 0.25 mg	5654A
69	Digitek (digoxin tablets, USP) 0.25 mg	5818A
70	Digitek (digoxin tablets, USP) 0.25 mg	5820A
71	Digitek (digoxin tablets, USP) 0.25 mg	60116A
72	Digitek (digoxin tablets, USP) 0.25 mg	60117A
73	Digitek (digoxin tablets, USP) 0.25 mg	60323A
74	Digitek (digoxin tablets, USP) 0.25 mg	60497A
75	Digitek (digoxin tablets, USP) 0.25 mg	60498A
76	Digitek (digoxin tablets, USP) 0.25 mg	60679A
77	Digitek (digoxin tablets, USP) 0.25 mg	60864A
78	Digitek (digoxin tablets, USP) 0.25 mg	60865A
79	Digitek (digoxin tablets, USP) 0.25 mg	61055A
80	Digitek (digoxin tablets, USP) 0.25 mg	61056A
81	[redacted]	
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Item	Product Name	Batch #
85	[redacted]	
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143	[redacted]	
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Item	Product Name	Batch #
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Item	Product Name	Batch #
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Item	Product Name	Batch #
316	[redacted]	
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